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Total Number of Pages in This Submission

6

Application Number	10/538589-Conf. #9056
Filing Date	June 15, 2005
First Named Inventor	Thomas SMITH
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	0112981.00125US36

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/Incomplete Application
- ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53

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- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):
 - Return Receipt Postcard
 - 27 nonpatent publications
 - Form PTO SB/08

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	WILMER CUTLER PICKERING HALE AND DORR LLP		
Signature			
Printed name	Michael J. Twomey		
Date	June 26, 2006	Reg. No.	38,349

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Signature: Stephen R. Douglas

Docket No.: 0112981.00125US36
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas SMITH Confirmation No.: 9056
Application No.: 10/538589 Art Unit: N/A
Filed: June 15, 2005 Examiner: Not Yet Assigned
Title: COATED PARTICLES FOR SUSTAINED-RELEASE
PHARMACEUTICAL ADMINISTRATION

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Respectfully submitted,

Dated: June 26, 2006

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Attorney Docket Number	0112981.00125US36

Sheet	1	of	4
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
M.Y.	AA*	US-2,515,898	07-18-1950	Rhodehamel	
	AB*	US-2,627,491	02-03-1953	Szabo et al.	
	AC*	US-3,993,073	11-23-1976	Zaffaroni	
	AD*	US-4,105,776	08-08-1978	Ondetti et al.	
	AE*	US-4,231,938	11-04-1980	Monaghan et al.	
	AF*	US-4,316,906	02-23-1982	Ondetti et al.	
	AG*	US-4,337,201	06-29-1982	Petrillo, Jr.	
	AH*	US-4,344,949	08-17-1982	Hoefle et al.	
	AI*	US-4,346,227	08-24-1982	Terahara et al.	
	AJ*	US-4,374,829	02-22-1983	Harris et al.	
	AK*	US-4,410,520	10-18-1983	Watthey	
	AL*	US-4,439,196	03-27-1984	Higuchi	
	AM*	US-4,444,784	04-24-1984	Hoffman et al.	
	AN*	US-4,508,729	04-02-1985	Vincent et al.	
	AO*	US-4,512,924	04-23-1985	Altwood et al.	
	AP*	US-4,587,258	05-06-1986	Gold et al.	
	AQ*	US-4,652,441	03-24-1987	Okada et al.	
	AR*	US-4,675,196	06-23-1987	Villa et al.	
	AS*	US-4,739,073	04-19-1988	Kathawala	
	AT*	US-4,757,128	07-12-1988	Domb et al.	
	AU*	US-4,789,724	12-06-1988	Domb et al.	
	AV*	US-4,857,311	08-15-1989	Domb et al.	
	AW*	US-4,888,176	12-19-1989	Langer et al.	
	AX*	US-4,897,402	01-30-1990	Duggan et al.	
	AY*	US-4,906,624	03-06-1990	Chucholowski et al.	
	AZ*	US-4,906,657	03-06-1990	Roth	
	AA1*	US-4,904,646	02-27-1990	Karanewsky et al.	
	AB1*	US-4,920,109	04-24-1990	Onishi et al.	
	AC1*	US-4,923,861	05-08-1990	Picard et al.	
	AD1*	US-4,929,620	05-29-1990	Chucholowski et al.	
	AE1*	US-4,939,143	07-03-1990	Regan et al.	
	AF1*	US-4,940,727	07-10-1990	Inamine et al.	
	AG1*	US-4,940,800	07-10-1990	Bertolini et al.	
	AH1*	US-4,946,860	08-07-1990	Morris et al.	
	AI1*	US-4,946,864	08-07-1990	Prugh et al.	
	AJ1*	US-4,950,675	08-21-1990	Chucholowski	
	AK1*	US-4,957,940	09-18-1990	Roth	
	AL1*	US-4,963,538	10-16-1990	Duggan et al.	
	AM1*	US-4,968,693	11-06-1990	Joshua et al.	
	AN1*	US-4,970,231	11-13-1990	Lee et al.	
	AO1*	US-4,992,429	02-12-1991	Ullrich et al.	
	AP1*	US-4,994,281	02-19-1991	Muranishi et al.	
	AQ1*	US-4,994,494	02-19-1991	Regan et al.	
	AR1*	US-4,996,234	02-26-1991	Regan et al.	
M.Y.	AS1*	US-4,997,837	03-05-1991	Chucholowski et al.	

Examiner Signature	/Micah Paul Young/ (09/21/2009)	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/538589-Conf. #9056	
			Filing Date	June 15, 2005	
			First Named Inventor	Thomas SMITH	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	4	Attorney Docket Number	0112981.00125US36

AT1*	US-5,001,128	03-19-1991	Neuenschwander et al.
AU1*	US-5,001,144	03-19-1991	Regan et al.
AV1*	US-5,017,716	05-21-1991	Karanewsky et al.
AW1	US-5,021,453	06-04-1991	Joshua et al.
AX1*	US-5,025,000	06-18-1991	Karanewsky
AY1*	US-5,081,136	01-14-1992	Bertolini et al.
AZ1*	US-5,091,378	02-25-1992	Karanewsky et al.
AA2*	US-5,091,386	02-25-1992	Kesseler et al.
AB2*	US-5,098,931	03-24-1992	Duggan et al.
AC2*	US-5,102,911	04-07-1992	Lee et al.
AD2*	US-5,112,857	05-12-1992	Vickers
AE2*	US-5,116,870	05-26-1992	Smith et al.
AF2*	US-5,130,306	07-14-1992	Duggan et al.
AG2*	US-5,132,312	07-21-1992	Regan et al.
AH2*	US-5,135,935	08-04-1992	Alberts et al.
AI2*	US-5,166,171	11-24-1992	Jendralla et al.
AJ2*	US-5,182,298	01-26-1993	Helms et al.
AK2*	US-5,196,440	03-23-1993	Bertolini et al.
AL2*	US-5,202,327	04-13-1993	Robl
AM2*	US-5,250,435	10-05-1993	Cover et al.
AN2*	US-5,256,689	10-26-1993	Chiang
AO2*	US-5,260,332	11-09-1993	Dufresne
AP2*	US-5,262,435	11-16-1993	Joshua et al.
AQ2*	US-5,273,995	12-28-1993	Roth
AR2*	US-5,276,021	01-04-1994	Karanewsky et al.
AS2*	US-5,283,256	02-01-1994	Dufresne et al.
AT2*	US-5,286,895	02-15-1994	Harris et al.
AU2*	US-5,302,604	04-12-1994	Byrne et al.
AV2*	US-5,317,031	05-31-1994	MacConnell et al.
AW2	US-5,356,896	10-18-1994	Kabadi et al.
AX2*	US-5,369,125	11-29-1994	Berger et al.
AY2*	US-5,378,475	01-03-1995	Smith et al.
AZ2*	US-5,385,932	01-31-1995	Vickers
AA3*	US-5,618,563	04-08-1997	Berde et al.
AB3*	US-5,622,985	04-22-1997	Olukotun et al.
AC3*	US-5,639,480	06-17-1997	Bodmer et al.
AD3*	US-5,651,990	07-29-1997	Takada et al.
AE3*	US-5,700,485	12-23-1997	Berde et al.
AF3*	US-5,922,340	07-13-1999	Berde et al.
AG3*	US-6,046,187	04-04-2000	Berde et al.
AH3*	US-6,214,387	04-10-2001	Berde et al.
AI3*	US-6,238,702	05-29-2001	Berde et al.
AJ3*	US-6,326,020	12-04-2001	Kohane et al.
AK3*	US-6,426,339	07-30-2002	Berde et al.

FOREIGN PATENT DOCUMENTS

Examiner	Foreign Patent Document	Publication	Pages, Columns, Lines,
Signature	/Micah Paul Young/ (09/21/2009)	Date Considered	09/21/2009



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			Filing Date	June 15, 2005	
			First Named Inventor	Thomas SMITH	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	4	Attorney Docket Number	0112981.00125US36

Initials*	Cite No. ¹	Country Code ² -Number ³ -Kind Code ⁴ (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁵

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume- issue number(s), publisher, city and/or country where published	T ⁵
/M.Y./	CA	ADAMS et al., Depot fluphenazine for schizophrenia, Cochrane Database Syst. Rev. 2000	
/M.Y./	CB	ARNSTEN et al., Antiretroviral therapy adherence and viral suppression in HIV-infected drug users: comparison of self-report and electronic monitoring, Clin. Infect. Dis., 2001, pp.1417-23, 33(6)	
/M.Y./	CC	BARTLETT et al., Management of Anthrax, Clinical Infectious Diseases, 2002, pp.851-858, 35	
/M.Y./	CD	BLAUW et al., Stroke statins and cholesterol, A meta-analysis of randomized, placebo-controlled, double-blind trials with HMG-CoA reductase inhibitors, Stroke 1997, pp.946-50, 28(5)	
/M.Y./	CE	BURCH et al., Current indications for ACE inhibitors and HOPE for the future, Am. J. Mang. Care, 2002, pp.478-90, quiz 491-3, 8(5)	
/M.Y./	CF	BYRON et al., Effects of heat treatment on the permeability of polyvinyl alcohol films to a hydrophilic solute, J. Pharm. Sci., 1987, pp.65-67, 76(1)	
/M.Y./	CG	CADORNIGA et al., In vitro evaluation of the dissolution rate of crystalline suspensions destined to intramuscular administration, Eur. J. Drug Metab. Pharmacokin, 1991, pp.379-84, Spec. No. 3	
/M.Y./	CH	CUSHENBERRY et al., Potential use of HMG-CoA reductase inhibitors for osteoporosis, Ann. Pharmacother, 2002, pp.671-8, 36(4)	
/M.Y./	CI	DECHEND et al., Modulating angiotensin II-induced inflammation by HMH Co-A reductase inhibition, Am. J. Hypertens., 2001, pp.55S-61S, 14(6 Pt2)	
/M.Y./	CJ	ENDRES et al., Stroke protection by 3-hydroxy-3-methylglutaryl (HMG)-CoA reductase inhibitors mediated by endothelial nitric oxide synthase, Proc. Nat. Acad. Sci. USA, 1998, pp.8880-5, 95	
/M.Y./	CK	FASSBENDER et al., Effects of statins on human cerebral cholesterol metabolism and secretion of Alzheimer amyloid peptide [in process citation], Neurology, 2002, pp.1257-8, 59(8)	
/M.Y./	CL	FLECKENSTEIN, History of calcium antagonists, Cir. Res./Suppl. 1, 1983, pp.1-3-1-16, 52(2)	
/M.Y./	CM	FRIEDLANDER et al., Postexposure prophylaxis against experimental inhalation anthrax, J. Infect. Dis., May 1993, pp.1239-43, 167(5)	
/M.Y./	CN	GHARABAWI et al., Enhanced psychiatric and neurological outcomes in chronically psychotic patients treated for a year with long-acting, injectable risperidone, Proc. Ann. Meeting Am. College of Neuropsychopharmacology, 2002, San Juan PR	
/M.Y./	CO	HOUGHTON, Angiotensin II receptor antagonists in chronic heart failure: where to they fit?, Drugs, 2002, pp.1433-40, 62(10)	
/M.Y./	CP	JEFFERDS et al., Adherence to antimicrobial inhalational anthrax prophylaxis among postal workers, Emerging Infectious Diseases, 2002, pp.1138-1144, 8(10)	
/M.Y./	CQ	KAPLAN et al., Pharmacokinetics of benzathine penicillin G: serum levels during the 28 days after intramuscular injection of 1,200,000 units, J. Pediatr., 1989, pp.146-50, 115(1)	

Examiner Signature	/Micah Paul Young/ (09/21/2009)	Date Considered	09/21/2009
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Application Number	10/538589-Conf. #9056		
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Examiner Name	Not Yet Assigned		
Attorney Docket Number	0112981.00125US36		
Sheet	4	of	4

/M.Y.	CR	MCCALL et al., Calcium entry blocking drugs: Mechanisms of action, experimental studies and clinical uses, Curr. Probl. Cardiol., 1985, pp.1-80	
/M.Y.	CS	MIMRAN et al., Angiotensin II receptor antagonists and hypertension, Clin. Exp. Hypertens., 1999, pp.847-58, 21(5-6)	
/M.Y.	CT	MOLLMANN et al., Clinical and pharmacologic aspects of various betamethasone crystalline suspensions, fortschr. Med., 1977, pp.972-8, 95(14)	
/M.Y.	CU	NICHOLS, Hormones and hormone antagonists, Remington: The Science and Practice of Pharmacy, 2000, p.1371	
/M.Y.	CV	O'KEEFE et al., Should an angiotensin-converting enzyme inhibitor be standard therapy for patients with atherosclerotic disease?, J. Am. Coll. Cardiol., pp.1-8, 37(1)	
/M.Y.	CW	PERICO et al., Angiotensin II receptor antagonists and treatment of hypertension and renal disease, Curr. Opin. Nephrol. Hypertens., 1998, pp.571-8, 7(5)	
/M.Y.	CX	QURAISHI et al., Depot haloperidol decanoate for schizophrenia, Cochrane Database Syst. Rev. 2000	
/M.Y.	CY	Remington: The Science and Practice of Pharmacy, p.963, 19th Edition	
/M.Y.	CZ	Table 16-1, Remington: The Science and Practice of Pharmacy, 2000, p.209, 20th Ed.	
/M.Y.	CA1	WONG et al., Nonpeptide angiotensin II receptor antagonists I. Pharmacological characterization of 2-n-butyl-4-chloro-1-(2-chlorobenzyl)imidazole-5-acetic acid, sodium salt (S-8307), J. Pharmacol. Exp. Ther., 1988, pp.1-7, 247(1)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Applicant's unique citation designation number (optional). *Applicant to place a check mark here if English language Translation is attached.

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